# A QUICK GUIDE TO PATENT LAW AND RECENT DEVELOPMENTS IN THE FIELD

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*Executive Summary: The framers of the U.S. Constitution believed that codifying intellectual property rights at the federal level was important to economic independence, innovation, and domestic growth. Article I, Section 8 declares that Congress has the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Intellectual property in the United States encompasses four broad categories: patents, trademarks, copyrights, and trade secrets. A patent is a property right granted to an inventor that allows the inventor (or assignee) to exclude others from "making, using, offering for sale, or selling" the invention for a limited time. Patents play an essential role in the economy by creating limited legal monopolies for inventors and developers, which incentivizes investment in creativity, innovation, and production. In exchange for these legal monopolies, patent owners disclose their inventions to the world, contributing to continued advancements in science, engineering, medicine, and more. A well-functioning and efficient patent system is critical to American invention and innovation.*

## I. BACKGROUND: WHAT IS A PATENT?

A patent is intended to protect new processes, machines, and/or products as codified in the 1952 Patent Act.[1] A patent is an exclusive right granted by the federal government to "exclude others from making, using, offering for sale, or selling" an invention throughout the United States and to exclude others from importing the invention into the United States.[2] To get a patent, technical information about the invention must be disclosed to the public in a patent application. As a reward for disclosing their invention to the public in a patent application, patent owners can obtain exclusive rights to their inventions for a certain time; however, a patent does not give the inventor an affirmative right to make, use, or sell the invention.[3] After a patent term expires, the patent owner loses the legal monopoly, and the patented subject matter becomes part of the public domain—meaning others are free to make, use, and sell the relevant products or process in the free market.[4]

Patent law finds its basis in the United States Constitution, which granted Congress the power "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[5] This clause, known as the Patent and Copyright Clause, is viewed both as a designation of an enumerated power to Congress and as a limitation on that power; specifically, the Constitution gave Congress the power to "grant[] exclusive rights for limited times."[6] This means patents only

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[1] 35 U.S.C. §§ 1–390.
[2] 35 U.S.C. § 154.
[3] CRAID ALLEN NARD, THE LAW OF PATENTS 1 (4th ed. 2017) ("A patent gives its owner the right to exclude; a patent does not provide a positive right to make, use, or sell, the invention.").
[4] *See* U.S. Patent Overview, FINDLAW (June 12, 2017), https:/corporate.findlaw.com/intellectual-property/u-s-patent-overview.html (explaining that, once a patent expires, anyone may make, use, offer for sale, or import the invention).
[5] U.S. CONST. art. I, § 8, cl. 8.
[6] NARD, *supra* note 3, at 18.

grant the right to exclude—thus giving its holder a legal monopoly—without other rights, and those rights must expire after some period of time. Congress has exercised its power to promote the sciences with many different patent laws, from the Patent Act of 1790,[7] its first patent statute, to the 2013 Leahy-Smith America Invents Act (AIA),[8] the first significant overhaul to the patent system in over fifty years.

Patents fall into one of three categories: utility patents, design patents, and plant patents.[9] Utility patents are the concern of most patent law proceedings. Utility patents protect functional ideas ("the way an article is used and works") and issue for a period of twenty years from the filing date of the patent application.[10] Design patents "protect[] the way an article looks" and issues for a period of fifteen years.[11] Plant patents generally protect "distinct and new variet[ies] of plant[s]" such as plants invented or discovered and asexually reproduced.[12]

Modern patent documents consist of two main parts: the specification and the claims.[13] As the Federal Circuit succinctly stated, "[s]pecifications teach. Claims claim."[14] The specification contains the disclosure of the invention which is used to teach the reader about the particulars of the invention.[15] However, the specification is not a "how-to" guide instructing the average person how to make or perform the invention but rather contains only enough detail for a person skilled in the art to carry out the invention.[16] In contrast, claims, which are "considered to be the most important part of the patent document," set the legal boundaries of the invention and precisely define the patentee's property rights.[17]

## II. BACKGROUND: HOW DO I GET A PATENT?

The patent application process, otherwise known as patent prosecution, starts when an inventor files a patent application with the United States Patent and Trademark Office

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[7] Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.
[8] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).
[9] U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 1502.01 (9th ed. Rev. 10, June 2020) (hereinafter MPEP).
[10] *Id.*
[11] *Id.*
[12] MPEP § 1601 (9th ed. Rev. 10, June 2020); G*eneral Information About 35 U.S.C. 161 Plant Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/types-patent-applications/general-information-about-35-usc-161 (last visited Sept. 24, 2024). Without plant patents, some kinds of agricultural development would not be cost effective, since anyone could simply get seeds of the plant and grow for free what the patent owner had spent time and effort designing.
[13] *See* Nard, *supra* note 3, at 47 (noting that claims are technically part of the specification under 35 U.S.C. § 112, but that patent professionals and courts treat claims and specifications as distinct).
[14] SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1984).
[15] *Id.* at 1122.
[16] Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005).
[17] *Id.* at 1118, 1121.

(USPTO).[18] After the application is received, it is sent to a particular art unit and Examiner who reviews the patent application for compliance with patent laws, namely, subject matter eligibility,[19] novelty,[20] non-obviousness,[21] and sufficient disclosure.[22] Patent prosecution generates a prosecution history, which refers to the record of all communications between the USPTO and the applicant regarding a particular filing.[23] The USPTO awards patents for *new* inventions; that is, patents cannot be issued for concepts and objects already in the public domain.[24] "Prior art" is the term used to refer to all inventions, writings, and patents that came before and are related to a particular application.[25] For the patent to be issued, it must be distinguishable from the prior art and meet all other statutory requirements.[26]

Three primary statutory requirements of patent eligibility include novelty, non-obviousness, and subject matter.[27] For an invention to be novel, it cannot have been disclosed in a patent, described in a printed publication, in public use, on sale, or otherwise available to the public prior to its effective filing date.[28] Similarly, a patentable invention must be non-obvious—that is, readily apparent or easily conceivable to a person of ordinary skill in the relevant field.[29] Finally, a patentable invention must refer to patentable subject matter, which is defined by statute as a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[30] Typically, subject matters that are not patentable include laws of

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[18] *See* Joshua Scheufler, Patent, 27 TEX. INTELL. PROP. L.J. 139, 140–41 (2019) (detailing the PTO process); *Trademark, Patent, or Copyright?*, U.S. PAT. & TRADEMARK OFF. (Oct. 15, 2019, 09:54 AM), https:/www.uspto.gov/trademarks-getting-started/trademark-basics/trademark-patent-or-copyright (explaining the difference between a patent and a copyright).

[19] Four categories of invention—process, machine, manufacture, or composition of matter—are deemed by Congress to be the appropriate subject matter of a patent. 35 U.S.C. § 101.

[20] The requirement for Novelty means that nothing exactly like the claimed invention can be found in the prior art. 35 U.S.C. § 102.

[21] Non-obviousness requires the applicant to demonstrate that they have given society something it didn't have before. The claimed invention must be a nonobvious solution to the person having ordinary skill in the art (PHOSITA). 35 U.S.C. § 103.

[22] Sufficient disclosure requires that a patent application disclose a claimed invention in sufficient detail so that the PHOSITA could carry out that claimed invention. 35 U.S.C. § 112.

[23] Karen Millane Whitney, *Sources of Patent Prosecution History Must Not Violate Public Notice Requirement*, 32 SETON HALL L. REV. 266, 266–68, 268 n.6 (2001).

[24] See Eileen M. Kane, Patent Ineligibility: Maintaining a Scientific Public Domain, 80 ST. JOHN'S L. REV. 519, 540 (2006) (explaining the public domain must be protected by not awarding patents to material already within the public domain).

[25] Whitney, *supra* note 23, at 269–70.

[26] *Id.*

[27] 35 U.S.C. §§ 101, 102, 103.

[28] 35 U.S.C. § 102(a).

[29] 35 U.S.C. § 103.

[30] 35 U.S.C. § 101.

nature,[31] natural phenomena,[32] and abstract ideas.[33]

## III. BACKGROUND: PATENT LAW JUDICIAL BODIES AND PROCEEDINGS

The Federal Circuit has exclusive subject matter jurisdiction over patent appeals and hears patent appeals from federal district courts, the International Trade Commission (ITC), and the Patent Trial and Appeals Board (PTAB).[34] In 2021, over fifty percent of the Federal Circuit docket consisted of patent related appeals with thirty-five percent coming from the USPTO, sixteen percent coming from district courts, and about four percent coming from the ITC.[35]

Under the AIA, the USPTO has substantially expanded its role in adjudicating the validity of patent claims. The Act created two new types of post-grant proceedings: Post-Grant Review[36] (PGR) and Inter Partes Review[37] (IPR). PGRs review the validity of a patent that has recently issued, allowing anyone to challenge a patent's validity within nine months of issuance on any ground.[38] The PTAB will grant review if it believes it is "more likely than not" at least one of the challenged claims is unpatentable on grounds such as subject matter, novelty, public use, or sale.[39] IPRs, on the other hand, permit challenges of a patent's validity after nine months from issuance or, if a party initiated a PGR proceeding, after the PGR terminates.[40] The scope of the challenge in an IPR is narrower than a PGR: grounds for invoking IPR are limited novelty and obviousness and with patents and printed publications.[41] Further, the court will not authorize an IPR unless there is a reasonable likelihood that the petitioner will prevail.[42] The decisions to institute both PGRs and IPRs are "final and not appealable;"[43] however, once instituted, a party may appeal an adverse result to the Federal Circuit. These two new methods of review,

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[31] *See, e.g.*, O'Reilly v. Morse, 56 U.S. 62, 113–14 (1853) (holding as ineligible a general claim for using electric current to transmit intelligible signals (telegraphy) because of its broad focus on a law of nature (electromagnetism)).
[32] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that a genetically engineered micro- organism was patentable because it did not otherwise exist in nature).
[33] *See, e.g.*, Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 226–27 (2014) (rejecting a patent claim as drawn to the abstract idea of intermediated settlement because the claim merely used a generic computer implementation).
[34] 28 U.S.C. § 1295(a); *see* NARD, *supra* note 3, at 42–43 (explaining that appeals to the Federal Circuit from PTAB may arise from the patent prosecution process, or from patent review proceedings such as Inter Partes and Post Grant Reviews).
[35] APPEALS FILED, BY CATEGORY, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (2021), https://cafc.uscourts.gov/wp-content/uploads/reportsstats/caseload-by category/Caseload_by_Category_FY2021.pdf.
[36] 35 U.S.C. § 321.
[37] 35 U.S.C. § 311.
[38] 35 U.S.C. § 321(c).
[39] 35 U.S.C. § 324(a).
[40] 35 U.S.C. § 311(c).
[41] 35 U.S.C. § 311(b).
[42] 35 U.S.C. § 314(a).
[43] 35 U.S.C. §§ 324(e), 314(d).

particularly IPRs, have been very popular due to their economy and efficiency for challenging patents.[44]

## IV. CURRENT PATENT NEWS & FURTHER READING

### A. PATENTS AND ARTIFICIAL INTELLIGENCE

Artificial Intelligence (AI) will affect procedural law greatly—evidence, civil procedure, legal ethics, and much more will have to accommodate AI.[45] Substantively, the field of Patent law will be affected the most.[46] Most basically, Patent law is about incentivizing inventors to create new and innovative inventions.[47] Innovation is so crucial to a society that the founders of this country placed it in the U.S. Constitution.[48] However, with the advent of AI, is this incentivization so crucial? Does AI make innovation not extraordinary but ordinary? How must the Patent system accommodate AI? These questions are at the forefront of every patent law theorist, and many are coming to different conclusions.

### B. PATENTS AFTER LOPER BRIGHT ENTERPRISES

In *Loper Bright Enterprises v. Raimondo*,[49] the Supreme Court overturned *Chevron* deference, which courts afforded to administrative agencies when delegation statutes were deemed ambiguous.[50] In Patent law, two main administrative agencies are in play—the U.S. Patent and Trademark Office (USPTO) and the U.S. International Trade Commission (ITC).[51] These agencies are involved in highly technical policymaking, rulemaking, and fact finding. Following *Loper Bright*, the USPTO's and the ITC's procedures and regulations will likely be challenged much more frequently and will be much more susceptible to such challenges as the agencies will not be afforded any deference for the interpretations of their governing statutes.[52] Many experts suspect this will greatly affect post-grant proceedings at the USPTO and section

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[44] NARD, *supra* note 3, at 45.
[45] *See* Paul W. Grimm, Maura R. Grossman, & Gordon V. Cormack, *Artificial Intelligence as Evidence*, 19 NW. J. TECH. & INTELL. PROP. 9 (2021).
[46] *See* Abbott Lab'ys v. Sandoz, Inc., 544 F.3d 1341, 1352 (Fed. Cir. 2008) ("Each [patent eligibility] case must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest.").
[47] *See* U.S. CONST. art. I, § 8, cl. 8 (Congress has the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.").
[48] *Id.*
[49] Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (2024).
[50] *Id.* at 2273.
[51] *Supra* Section III.
[52] In overruling *Chevron*, the Court eliminated the requirement that courts give deference to agency decisions. *See Loper Bright Enters.*, 144 S. Ct. at 2265, 2273.

337 litigation at the ITC.[53] However, only time will tell, as *Loper Bright* expressly did not call into question previous decisions relying on *Chevron* deference and individual challenges to the USPTO and ITC procedures and regulations are required for change.

### C. Pharmaceutical Patents as Related to March-In Rights

The Bayh-Dole Act allows universities, nonprofits, and small businesses to use federal funds to develop, own, and commercialize inventions.[54] However, because these inventions were created pursuant to federal funding, the government retains a "march-in" right to the invention, regardless of any patent on said invention.[55] Even though the government has never exercised a "march-in" right, the Bayh-Dole Act makes clear that these rights can be appropriately utilized when a federally funded invention has too high a market price.[56] Thus, many scholars have advocated for the government to use these "march-in" rights on federally funded pharmaceuticals to lower pharmaceutical prices across the United States.[57] Essentially, because these pharmaceuticals were invented through the use of federal funds, the government can "march-in" and make the patent holder license its patent to other parties, thereby reducing the price of products covered by the invention.[58]

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[53] *See* Frank M. Gasparo, Ralph A. Dengler, Gianna E. Cricco-Lizza, & Parker G. Zimmerman, *Loper Decision Impact on Patent Law*, VENEBLE LLP (July 10, 2024), https://www.venable.com/insights/publications/2024/chevron-decision/loper-decision-impact-on-patent-law.
[54] Bayh-Dole Act of 1980, Pub. L. No. 96-517.
[55] *Id.*
[56] *Id.*
[57] *See* Rebecca Eisenberg & Arti K. Rai, *Bayh-Dole Reform and the Progress of Medicine*, 66 J. L. & CONTEMP. PROBS. 289 (2002); Varoon Mathur, *Will Bayh-Dole be Needed to Get Affordable Covid-19 Treatments?*, STAT (Apr. 2, 2020), https://www.statnews.com/2020/04/02/invoking-bayh-dole-may-be-needed-to-get-affordablecovid-19-treatments/.
[58] Bayh-Dole Act of 1980, Pub. L. No. 96-517.